American Red Cross

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December 3, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Draft Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations [69 FR 59239, October 4, 2004; Docket No. 2004D-0443]

Dear Docket Officer:

The American Red Cross (Red Cross) appreciates this opportunity to provide public comments concerning the Food and Drug Administration's (FDA or Agency) draft guidance entitled "Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations" (Hereafter, referred to as "the Draft Guidance").

The Red Cross is committed to the safety of donors and patients, and to meeting the best interests of the public we serve. Through its thirty-six Blood Services regions, the Red Cross supplies approximately half of the nation's blood for transfusion needs. The plasma donated by Red Cross volunteers is recovered from whole blood and further processed or fractionated into plasma derivatives.

The Red Cross fully supports the intent of the Draft Guidance to describe a comprehensive quality system (QS) model that is consistent with current Good Manufacturing Practices (cGMP). Red Cross is fully committed to compliance with all applicable regulations and guidances, and strives to utilize quality systems to ensure compliance with cGMP. Moreover, as part of its compliance efforts, the Red Cross has devoted a significant amount of time and resources to the development of a comprehensive quality systems model. Based on that experience, we offer the following comments for your consideration.

1. Red Cross recommends that FDA clarify the scope of the Draft Guidance

Section II.C, "Scope of the Guidance," states that the Draft Guidance "applies to manufacturers of drug products (finished pharmaceuticals), including products regulated by the Center for Biologics Evaluation and Research (CBER)...." Blood and blood products are regulated as both biologics and pharmaceuticals and are subject to 21 CFR Subpart F (Part

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600 et. seq.) and 21 CFR Parts 210 and 211. The Draft Guidance contains only one specific reference to blood and blood products, in a footnote regarding CDER and CBER's inspectional approach (footnote 9). Because the quality system model represents a paradigm shift, it is imperative that the Draft Guidance be as clear as possible. In order to avoid confusion within the blood banking community, and to enable blood establishments to develop robust quality systems, Red Cross recommends that the Draft Guidance provide specific language regarding the applicability of the quality systems model in the blood establishment context.

An example of the need for such clarification is as follows: In section IV. C. 3 of the Draft Guidance, the Agency discusses the need to ensure that all inputs to the manufacturing process are reliable. The Draft Guidance then suggests means by which this can be accomplished, i.e., through verification of a supplier's COA and audits of the supplier. While this approach is appropriate and relevant for chemical ingredients, containers and closures, it is not applicable to blood establishment evaluation of "input", e.g., determination of donor suitability.

If the agency determines that these types of issues are too specific for a guidance of general applicability, Red Cross suggests that FDA develop a specific guidance discussing the quality systems approach in blood establishments.

2. Red Cross recommends that the FDA clarify the relationship between the Draft Guidance and FDA's "Guideline for Quality Assurance in Blood Establishments."

The Guideline for Quality Assurance in Blood Establishments describes the applicable quality assurance activities for manufacturers of blood and blood components. Red Cross believes that FDA should clarify the relationship between this document and the Draft Guidance, and the expectations that FDA has for quality systems in Blood Establishments.

The Draft Guideline describes a model approach to the organization of a quality system, whereas the "Guideline for Quality Assurance in Blood Establishments" describes specific systems that must be in place. Is the Draft Guidance intended to supercede the "Guideline for Quality Assurance in Blood Establishments?" If the two documents are intended to supplement each other, which document governs if there is a conflict?

Since 1999, AABB has encouraged its members to adopt a systems approach comprised of ten quality systems elements (QSEs) that are critical for producing consistent blood and blood components. AABB-accredited facilities, including Red Cross, already have these ten QSEs in place. The AABB approach represents industry consensus within the blood banking community for quality systems for the manufacture of blood and blood components. To avoid confusion in blood establishments, we believe that there should be consistency between FDA's Draft Guidance and AABB's quality systems approach.

3. Red Cross recommends that terms defined in the Glossary of the Draft Guideline be reviewed for harmonization with other FDA quality guidelines and documents.

Red Cross compared terms in the Glossary of the Draft Guideline with terms defined in 21 CFR 820.3; the "Guideline for Quality Assurance in Blood Establishments" mentioned above; and also with terms defined in Red Cross' Problem Management System which was reviewed and approved by FDA, as examples of documents that contain quality terms. In some instances the definitions are similar, but slightly different. For example, the definition of "non-conformity" that appears in 21 CFR 820.3 and the definitions of "Quality," "Quality Assurance," and "Quality Control" that appear in the 1995 Quality Assurance guideline are different from the same terms in the Draft Guideline and may lead to confusion.

The Red Cross appreciates this opportunity to provide public comments on the Draft Guidance. If you have any further questions or require follow-up, please contact Richard S. Robinson, Director, Technical Policy and Promotions at 202-303-5867 (phone), 202-303-0106 (fax) or RobinsonR@usa.redcross.org (e-mail).

Sincerely,

C. William Cherry
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